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| 09/925,618 | 08/10/2001 | Johannes Platzek | SCH-1774 | 2982 |

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| EXAMINER |
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HARTLEY, MICHAEL G

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/925,618

Applicant(s)

PLATZEK ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Response to Amendment

The preliminary amendment filed 12/18/2001 has been entered. Claims 3, 4, 8, 10-12, 20-22, 29, 30, 37, 44 and 45 have been amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-50 provide for the use of the use of perfluoroalkyl containing metal complexes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The claims contain various undefined variables and/or variables which are defined but not shown, for example:

Claim 8 is rejected because various variables are either undefined or defined but not shown. The variable R^3 is defined, but not present in the claimed formula. Also, R^a is defined to "have the above-indicated meanings" however, no previous indicated meaning is recited. Further, the definition of R^1 is confusing because this definition include a metal ion, but the formula shows this variable attached to a nitrogen by a covalent bond which would not form with such a metal.

Claim 9 is indefinite because the linkers, "L" recited in this claim are not encompassed by base claim 8. For example the linker of base claim 8 requires at least a group of $-(R^1)-N-SO_2-$ which is not present on many of the linkers in claim 9. Also, the linker in base claim 8 does not allow for many of the substituents present on the linkers of claim 9, such as fluorine atoms, phenylene groups, etc.

Claim 12 is indefinite because various variables are either undefined or defined but not shown. For example q^1 is defined, but not present in the claimed formula. Variables "G" and "Y" are shown but

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not defined. Variable "V" is not shown. Variables "Z" and "R¹" are not defined. Variables R⁶ and D are not shown.

In claim 14, it is unclear where variable D is in the formula.

In claim 15 it is unclear where variable V is in the formula.

Claims 16-18 define "U³" but only "U" is present in the formula and not "U³" and it is unclear if they are the same or different.

In claim 22, the formula of "(Ib) is unreadable (e.g., mainly because it is too small to be read) and therefore it is unclear what is being claimed.

In claims 24 and 25, the recitation of "and if necessary, their branched isomers" in the definition of "E" is confusing because it is unclear how a "hydrogen, fluorine, chlorine, bromine or iodine" (as E is defined) may have branched isomers, as they are single atoms. Also, it is unclear when "if necessary" would be met.

In claim 45, the recitation of "complexes of general formulas I, Ia, Ib, Ic and/or Id and diamagnetic perfluoroalkyl-containing substances" is confusing because these formulas are not shown or present in the base claim, claim 1.

In claim 49, the recitation of "conjugates that consist of...cyclodextrin and compound of general formula is confusing because it is unclear where the cyclodextrin is attached to the compound of the formula, since the formula is completely substituted. The point of conjugation of the cyclodextrin is unclear and therefore it is unclear how this recitation modifies the formula as claimed. Also, A² is defined in the claim, but not present in the formula, while A¹ is present by not shown. Thus, the scope of this claim cannot be determined.

In claim 50, the recitation of "(n in this case is a number between 1 and 10)" is confusing because there is no "n" shown in the formula. Also, many of the formula recited in this claim are missing bonds due to a photocopying problem. Thus, the formulae cannot be determined.

The dependent claims fall therewith.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-50 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

While the claims are drawn to a "use" they were examined only to the extent of a method of MRI of plaques (in combination with other tissues), as is the use as defined in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek, WO 97/26017 (US equivalent US 6,468,502, relied on for cited pertinent disclosures).

Platzek discloses methods of MRI comprising administering perfluoroalkyl substituted metal complexes, see abstract. The complexes have the formula as set forth in claim 1, which is the same as set forth in claims 8-11 of the present application. Since these complexes are the same as those set forth in claims 8-11, they must inherently have the same functional properties as those claimed (i.e., as claimed in claims 1-7). Same compounds must have same properties. Applicant admits the compounds in claims 8-11 are the same as set forth in WO 97/26017, see page 10 of the specification. Also, these complexes include substitution encompassed by "hydrophilic group" (e.g., due to hydroxy, etc.

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substitution). Platzek teaches that the complexes may be used to imaging various tissues, such as, vascular tissues, ischemic tissues, infarctions, lymph tissues, etc, see columns 2-3. Platzek teaches that the complexes are extremely well suited for imaging the vascular diseases since they disperse therein after administration, see column 2, lines 45+. These are the same tissues which are claimed.

Platzek fails to specifically disclose that the methods of MRI are used to image plaques, as claimed.

It would have been obvious to one of ordinary skill in the art to have employed the methods disclosed by Platzek to image plaques because Platzek specifically teaches that the methods are extremely well suited for imaging the vascular diseases since they disperse therein after administration, such as, infarction, etc., and plaques are clearly a vascular disease and directly related to infarction. One of ordinary skill in the art would have been motivated to employ the methods disclosed by Platzek to any vascular disease, such as, plaques, given the teaching that such methods are extremely well suited therefore.

Claims 1-7, 12-29 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek, WO 99/01161 (US equivalent US 6,019,595, relied on for cited pertinent disclosures).

Platzek discloses methods of MRI comprising administering perfluoroalkyl substituted metal complexes, see abstract. The complexes have the formula as set forth in columns 2+, which is the same as set forth in claims 12-29 of the present application. Since these complexes are the same as those set forth in claims 12-29, they must inherently have the same functional properties as those claimed (i.e., as claimed in claims 1-7). Same compounds must have same properties. Applicant admits the compounds in claims 12-29 are the same as set forth in WO 97/26017, see page 10 of the specification. Also, these complexes include substitution encompassed by "hydrophilic group" (e.g., due to hydroxy, etc. substitution). Platzek teaches that the complexes may be used to imaging various tissues, such as, vascular tissues, ischemic tissues, infarctions, lymph tissues, etc, see columns 3-4. Platzek teaches that the complexes are extremely well suited for imaging the vascular diseases since they disperse therein after administration, see paragraph bridging columns 3-4. These are the same tissues which are claimed.

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Platzek fails to specifically disclose that the methods of MRI are used to image plaques, as claimed.

It would have been obvious to one of ordinary skill in the art to have employed the methods disclosed by Platzek to image plaques because Platzek specifically teaches that the methods are extremely well suited for imaging the vascular diseases since they disperse therein after administration, such as, infarction, etc., and plaques are clearly a vascular disease and directly related to infarction. One of ordinary skill in the art would have been motivated to employ the methods disclosed by Platzek to any vascular disease, such as, plaques, given the teaching that such methods are extremely well suited therefore.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 30-36 and 45-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/925,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn methods of using the same perfluoroalkyl containing complexes. The claims of the copending application have various "use" claims including imaging vascular tissues, etc. It would have been obvious to one of ordinary skill in the art to use the methods of the copending application for plaques because the claims are specifically directed to imaging vascular tissues which include plaques therein. Additionally, the species set forth in the copending applications are directly within the scope of the genus claims 1-7 of the present application.

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Claims 1-7 and 37-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/925,420. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn methods of using the same perfluoroalkyl containing complexes. The claims of the copending application have various "use" claims including imaging vascular tissues, etc. It would have been obvious to one of ordinary skill in the art to use the methods of the copending application for plaques because the claims are specifically directed to imaging vascular tissues which include plaques therein. Additionally, the species set forth in the copending applications are directly within the scope of the genus claims 1-7 of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

The disclosure is objected to because of the following informalities: The specification contain numerous figures i.e., photographs, on at least pages 430-436, 438-440, 442-445, 447-450, 454, 456, 457 and 459. Such figures are not allowed in the specification.

Appropriate correction is required.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). The specification incorporates various chemical formulae etc. as claimed (e.g., clearly essential subject matter) by reference to foreign application(s) on page 10, which references two WO patents.

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The attempt to incorporate subject matter into this application by reference to claim is improper because claims can be amended and therefore be changed. For example, the specification incorporates the formula of the complexes from the claims into the specification.

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because many of the formulae or chemical moieties on pages 16, 27, 28 and 70 cannot be determined because of problems with photocopying or printing. These formulae are missing bonds and/or atoms and it is unclear.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 08/11/2000. It is noted, however, that applicant has not filed a certified copy of the 10040380.8 as required by 35 U.S.C. 119(b).

Conclusion

Claims 30-45 and 49-50 are free of the art of record. However, these claims are rejected under double patenting and 35 USC 112, second paragraph, as set forth above. However, the search was only performed to the best ability, given the lack of defined variables in some of the claims (e.g., claim 49).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this

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application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
February 7, 2003